

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
K. Roger Aoki

Examiner:
Anish Gupta

Serial No.: 10/726,904

Group Art Unit: 1654

Filed: December 2, 2003

Confirmation No. 4172

For: **USE OF THE NEUROTOXIC COMPONENT OF A BOTULINUM TOXIN
FOR TREATING A SPASTIC MUSCLE**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INTERVIEW SUMMARY AND AMENDED CLAIMS

This is applicants summary of the May 23, 2007 examiner interview regarding this application. Applicants also provide herein amended claims, as discussed at the interview. Claims 1, 5 and 29 are amended. Claims 30, 46 and 62 are cancelled

I. Interview Summary

A personal interview took place between the undersigned (the attorney of record in this application) and primary examiner Anish Gupta on Wednesday, May 23, 2007 from 9:20 am to 10:30 a.m. in the examiner's office in the Remsen building located at 400 Delany Street, Alexandria, Virginia.

Although several agreements were reached at the interview the examiner said that these are tentative agreements subject to the examiner's further review of the file. Similarly the lack of agreement with regard to point 3 below is a tentative lack of agreement also subject to the examiner's further review of the file.

Applicants summarize the interview as follows.

1. the examiner suggested amending the claims to state that the neurotoxic component used in the claimed method "has a molecular weight of about 150 kilodaltons" to thereby clarify that in the claimed method the neurotoxic component is administered by itself, not as a part of a larger botulinum toxin complex. It was agreed that if this limitation is added to the claims, then the limitation applicants had added to the claims in the response filed April 12, 2007 ("wherein the neurotoxic component administered to the patient has been purified from a botulinum toxin obtained by fermenting *Clostridium botulinum*") would not be needed in order to clearly limit the claimed method to use of just the neurotoxic component.

2. the examiner agreed that the arguments and evidence presented in applicants April 12, 2007 response overcome the rejection of the claims under 35 U.S.C. section 112, first paragraph for lack of written description.

3. the examiner expressed his view that the arguments and evidence presented in applicants April 12, 2007 response do not overcome the rejection of the claims under 35 U.S.C. section 112, first paragraph for lack of enablement.

The examiner views the reference Schantz et al, *Properties and use of botulinum toxin and other microbial neurotoxins in medicine*, Microbiol Rev 1992 Mar; 56(1): 80-89 ("Schantz 1992") as being an important reference close to applicant's December 28, 1993 effective filing date and over which the claimed invention is not enabled. The examiner said that applicants should consider providing a prior art reference which is concurrent with or after the publication date of Schantz 1992 yet before applicants December 1993 effective filing date which discloses or teaches effective use of a formulation which comprises as the active ingredient just the neurotoxic component of a botulinum toxin so as to countervail what the examiner believes is the negative effect of Schantz 1992 on the enablement of the claimed invention.

Applicants representative expressed the view that the extensive arguments and case law explanations presented in the April 12, 2007 response and in particular paragraphs 17-19 of the Brin declaration show that the claimed invention is enabled and that therefore the rejection of the claims for lack of enablement under 35 U.S.C. section 112, first paragraph should be withdrawn.

4. the examiner agreed that if enablement of the claimed subject matter is shown, then priority of the claims to the parent application's December 28, 1993 filing date will be granted and the rejection of claims under 35 U.S.C. section 103(a) as being unpatentable over the combinations of: (1) Balkan (1991) or Han (2001) in view of Tse (1982) and Aoki (U.S. patent 6,113,915 filed in 1999), and; (2) Balkan (1991) or Han (2001) in view of Aoki (U.S. patent 6,113,915 filed in 1999) and Aoki (2001 018415) will all be withdrawn because all the combinations contain one or more references which will then not be prior art with regard to the claims.

II. Amended Claims

As suggested by the examiner, applicants have amended all the independent claims in this application (claims 1, 5 and 29) so that all claims are limited to use of a neurotoxic component which has "a molecular weight of about 150 kilodaltons". Support for this claim limitation can be found at at least page 3, lines 5-6 of the specification of parent application serial number 08/173,996 filed December 28, 1993. The examiner suggested this claim limitation, as an alternative to the claim limitation applicants had added to all claims in the response filed April 12, 2007 ("wherein the neurotoxic component administered to the patient has been purified from a botulinum toxin obtained by fermenting *Clostridium botulinum*"), so as to clearly limit the claimed subject matter to administration of the neurotoxic component by itself, separate from the rest of the botulinum toxin complex.

Claims 30, 46 and 62 are hereby cancelled without prejudice to further prosecution at a later date.

Applicants wish to thank the examiner for his time and consideration of this application. Applicants believe that considerable progress was made at the interview in advancing the status of the application with regard to the claimed subject matter.

Respectfully submitted,
/STEPHEN DONOVAN.

Dated: June 1, 2007

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